



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : GOODWIN, J., et al.
Serial Number : 09/627,566
Filed : July 28, 2000
For : Covered Stent and Method of Covering A Stent

Group Art Unit : 3731
Examiner : BUI, VY Q
Paper Number :

Docket Number : ATA-286RCE

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TECHNOLOGY CENTER R3700

AFFIDAVIT UNDER 37 CFR 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

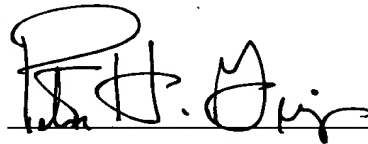
Peter H. Gingras, being duly sworn, deposes and says:

1. I, along with Jonathan L. Goodwin and Gary A. Jordan, am the inventor of claims 1-4 and 6-9 of the pending application identified above, and of the subject matter described and claimed therein.
2. Prior to August 5, 1998, I had completed my invention as described and claimed in the subject application in the United States of America, as evidenced by the following:
 - a. Prior to August 5, 1998, and having earlier conceived the idea of creating a radially deployable stent having a covering of biocompatible material on an inner surface of the stent and additional covering of biocompatible material on an outer surface of the stent, wherein at least one of the inner and outer coverings has a predetermined thickness and has an average internodal distance (IND) of greater than 100 microns to reduce a deployment pressure necessary to expand the stent

to less than 10 atmospheres, I expanded a coated stent (ID# RD808617) with a 7 mm balloon at 6-7 atm, as evidenced by Exhibit A. The stent (ID# RD808617) coating had an internodal distance measurement of 118 microns +/- 33 microns as shown in Exhibit B. The stent (ID# RD808617) experienced no tears as evidenced by Exhibit A.

b. The above described actions involved use of a stent wherein one of the inner and outer coverings has a predetermined thickness and has an average internodal distance (IND) of greater than 100 microns having a deployment pressure necessary to expand the stent of less than 10 atmospheres.

3. Each of the dates deleted from Exhibits A and B is prior to August 5, 1998.

 25 JUNE 2003
Peter H. Gingras

Sworn to and subscribed before me this _____ day of June, 2003.

(Notary Signed)

(Notary Printed Name)

(Notary Seal)

From Page No.

EXHIBIT A

Stent Covering RD808617 0.128"/0.088" 13:1
Compression Layer RD805504 0.118"/0.088" 6:1
Stent sleeve 0.156" / 0.128"
Cuff sleeve 0.148" / 0.128"
Mandrel 0.095"
AD-1 4:1 - (water / AD1)

- Wipe down the mandrels with alcohol
- Cut the covering and compression layer to 150mm lengths.
- Plasma etch the covering (O₂ - 10 sec. - 50 watts - 0.150 Torr)
- Place the plasma etched covering on the mandrel and tie off one end with suture.
- Slide the stent over the sutured end and center the stent on the PTFE.
- With a Q-Tip lightly apply the AD1 to the stent and 0.5cm of the PTFE at both ends of the stent..
- Place the mandrel / stent in the Grieve oven (250°F - 20 min.) to dry
- Remove the suture and expand the end of the PTFE with a pair of tweezers, then place the cuff sleeve (0.148"/0.128") over the mandrel and under the PTFE until it reaches the stent, measure 20mm from the stent and trim off the excess PTFE.
- Gently slide the sleeve/PTFE over the stent to form the first cuff.
- Slide the stent to the opposite end of the mandrel and expand this end of the PTFE with a pair of tweezers, then place cuff sleeve (0.148"/0.128") over the mandrel and under the PTFE until it reaches the stent, measure 20mm from the stent and trim off the excess.
- Gently slide the sleeve/PTFE over the stent and the first cuff.
- Expand the compression layer with a 0.150" pin gauge.
- Slide the compression layer over the mandrel and covered stent, tie off one end with suture then slide the stent sleeves (0.156"/0.128") over the compression layer and center the sleeves over the stent.
- Sinter 360°C - 6 min. (water quench).
- Remove the stent sleeves.
- Twist the stent to release it from the mandrel.
- Remove the third layer (compression layer).

Stent ID #s RD808617-051178SHB → D

SHB → Expanded with a 7mm balloon in Body Temp (37°C) water bath at 6-7atm, then with a 9mm balloon.
Looks Good no tears or delamination

SHC & D - used for an animal study

To Page No.

Witnessed & Understood by me,

Date

Invented by

Date

Recorded by

TITLE

COALS SGT COVERING

PROJECT NO.

BOOK NO.

RF 97-2 EXHIBIT B

From Page No. _____

THE following test data was forwarded from Mertz
CARSAK:

RD 8080403 2798543	-	0.60
RD 8080903 2798543	-	0.50
RD 8080403 32798543	-	0.44

HAVE Mertz
FOR HARDCOPY
THE lot #'s
B/Wing.

SGH Measurements

mm

RD 808617	118 ± 33
RD 808618	143 ± 51
RD 808619	161 ± 59
RD 808620	120 ± 38

60 measurements
were taken.

THE results were FAMED in by Mertz CARSAK.
I will request HARDCOPY.

To Page No _____

Witnessed & Understood by me,

Date

Invented by

Date

Recorded by

